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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,374	04/17/2002	Marcus E. Carr, Jr	03230006AA	3657

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EXAMINER	
LEARY, LOUISE N	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,374	CARR, JR ET AL.	
	Examiner	Art Unit	
	Louise N. Leary	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-11 are pending in this application.

2. The finality of the office action mailed January 11, 2005 has been withdrawn in favor of the rejection given below.

3. The Appeal Brief submitted May 11, 2005 has been recorded and held in abeyance.

4. The obviousness-type double patenting rejections of claims 1-11 have been maintained in-part for reasons given below.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(I) Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-10 of U.S. Patent No. 5,293,772 in view of Ramsis et al (Pathophysiology of Haemostasis and Thrombosis, Vol. 28, No. 5, 1998) (ABSTRACT ONLY).

Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-10 of U.S. Patent No. 5,293,772. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim a method for identifying patients at risk for atherosclerosis; identifying patients having a bleeding risk; and a treatment monitoring method wherein a measurement on the blood sample is selectively determined by platelet contractile force or clot elastic modulus. Thus, the subject matter claimed in U.S. Patent No. 5,293,772 substantially overlaps with the subject matter claimed in the instant invention. Therefore, U.S. Patent No. 5,293,772 discloses or suggests the invention as claimed except for addressing "comparing said measurement to a control to identify a patient as being at risk for atherosclerosis, wherein said patient is identified to be at risk when said measurement is elevated relative to said control."

However, regarding the instant step of "comparing said measurement to a control to identify a patient as being at risk for atherosclerosis, wherein said patient is identified to be at risk when said measurement is elevated relative to said control", Ramsis et al disclose (1) comparing platelet activity measurements in a healthy control patient to platelet activity measurements in a patient with atherosclerosis and (2) disclose "[Conclusion: This study demonstrates that *platelets circulate in an enhanced activation*

state in asymptomatic atherosclerosis, which is closely related to the degree of endothelial cell damage as expressed by increased plasma levels of TM. The detection of *platelet activation can be used as a potential marker for oncoming atherosclerosis*.]". See the entire Abstract.

Therefore, it would have been obvious to one having ordinary skill in this art at the time this invention was made to provide the invention claimed because U.S. Patent No. 5,293,772 disclose the invention as claimed except for the "comparing platelet activity measurements in a control to a patient being at risk to atherosclerosis" step provided by Ramsis et al earlier.

(II) Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-10 of U.S. Patent No. 5,205,159 in view of Ramsis et al (Pathophysiology of Haemostasis and Thrombosis, Vol. 28, No. 5, 1998) (ABSTRACT ONLY).

Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-9 of U.S. Patent No. 5,205,159. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim a method for identifying patients at risk for atherosclerosis; identifying patients having a bleeding risk; and a treatment monitoring method wherein a measurement on the blood sample is selectively determined by platelet contractile force or clot elastic modulus. Thus, the subject matter claimed in U.S. Patent No. 5,205,159 substantially overlaps with the subject matter claimed in the

instant invention. Therefore, U.S. Patent No. 5,205,159 discloses or suggests the invention as claimed except for addressing "comparing said measurement to a control to identify a patient as being at risk for atherosclerosis, wherein said patient is identified to be at risk when said measurement is elevated relative to said control."

However, regarding the instant step of "comparing said measurement to a control to identify a patient as being at risk for atherosclerosis, wherein said patient is identified to be at risk when said measurement is elevated relative to said control", Ramsis et al disclose (1) comparing platelet activity measurements in a healthy control patient to platelet activity measurements in a patient with atherosclerosis and (2) disclose "[Conclusion: This study demonstrates that platelet circulate in an enhanced activation state in asymptomatic atherosclerosis, which is closely related to the degree of endothelial cell damage as expressed by increased plasma levels of TM. The detection of *platelet activation can be used as a potential marker for oncoming atherosclerosis*.]". See the entire Abstract.

Therefore, it would have been obvious to one having ordinary skill in this art at the time this invention was made to provide the invention claimed because U.S. Patent No. 5,205,159 disclose the invention as claimed except for the step of "comparing platelet activity measurements in a control to a patient being at risk to atherosclerosis" step provided by Ramsis et al earlier.

(III) Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-15 of U.S. Patent No. 4,986,964 in view of Ramsis et al (Pathophysiology of Haemostasis and Thrombosis, Vol. 28, No. 5, 1998) (ABSTRACT ONLY).

Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-15 of U.S. Patent No. 4,986,964. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim a method for identifying patients at risk for atherosclerosis; identifying patients having a bleeding risk; and a treatment monitoring method wherein a measurement on the blood sample is selectively determined by platelet contractile force or clot elastic modulus. Thus, the subject matter claimed in U.S. Patent No. 4,986,964 substantially overlaps with the subject matter claimed in the instant invention. Therefore, U.S. Patent No. 4,986,964 discloses or suggests the invention as claimed except for addressing "comparing said measurement to a control to identify a patient as being at risk for atherosclerosis, wherein said patient is identified to be at risk when said measurement is elevated relative to said control."

However, regarding the instant step of "comparing said measurement to a control to identify a patient as being at risk for atherosclerosis, wherein said patient is identified to be at risk when said measurement is elevated relative to said control", Ramsis et al disclose (1) comparing platelet activity measurements in a healthy control patient to platelet activity measurements in a patient with atherosclerosis and (2) disclose "[Conclusion: This study demonstrates that platelet circulate in an enhanced activation

state in asymptomatic atherosclerosis, which is closely related to the degree of endothelial cell damage as expressed by increased plasma levels of TM. The detection of *platelet activation can be used as a potential marker for oncoming atherosclerosis*.]". See the entire Abstract.

Therefore, it would have been obvious to one having ordinary skill in this art at the time this invention was made to provide the invention claimed because U.S. Patent No. 4,986,964 disclose the invention as claimed except for the step of "comparing platelet activity measurements in a control to a patient being at risk to atherosclerosis" step provided by Ramsis et al earlier.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(I). Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr (US 5,293,772)(1994) in view of Ramsis et al (Pathophysiology of Haemostasis and Thrombosis, Vol. 28, No. 5, 1998) (ABSTRACT ONLY).

Carr discloses or suggests a method for identifying patients at risk for atherosclerosis. Carr discloses method for identifying patients at risk for atherosclerosis; identifying patients having a bleeding risk; and a treatment monitoring method wherein a measurement on the blood sample is selectively determined by

platelet contractile force or clot elastic modulus. As a result, Carr discloses or suggests the claim limitations described in the present invention. Therefore, Carr discloses or suggests the invention as claimed except for addressing "comparing said measurement to a control to identify a patient as being at risk for atherosclerosis, wherein said patient is identified to be at risk when said measurement is elevated relative to said control."

However, regarding the instant step of "comparing said measurement to a control to identify a patient as being at risk for atherosclerosis, wherein said patient is identified to be at risk when said measurement is elevated relative to said control", Ramsis et al disclose (1) comparing platelet activity measurements in a healthy control patient to platelet activity measurements in a patient with atherosclerosis and (2) disclose "[Conclusion: This study demonstrates that platelet circulate in an enhanced activation state in asymptomatic atherosclerosis, which is closely related to the degree of endothelial cell damage as expressed by increased plasma levels of TM. The detection of *platelet activation can be used as a potential marker for oncoming atherosclerosis*.]". See the entire Abstract.

Hence, Carr discloses or suggests the invention claimed except for the step of "comparing platelet activity measurements in a control to a patient being at risk to atherosclerosis" step provided by Ramsis et al.

Therefore, it would have been obvious to one having ordinary skill in this art at the time this invention was made to provide the invention claimed because Carr discloses or suggests the invention as claimed except for the step of "comparing platelet

activity measurements in a control to a patient being at risk to atherosclerosis" step provided by Ramsis et al earlier.

(II). Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr (US 5,205,159)(1993) in view of Ramsis et al.

Carr discloses or suggests a method for identifying patients at risk for atherosclerosis. Carr discloses method for identifying patients at risk for atherosclerosis; identifying patients having a bleeding risk; and a treatment monitoring method wherein a measurement on the blood sample is selectively determined by platelet contractile force or clot elastic modulus. As a result, Carr discloses or suggests the claim limitations described in the present invention. Therefore, Carr discloses or suggests the invention as claimed except for addressing "comparing said measurement to a control to identify a patient as being at risk for atherosclerosis, wherein said patient is identified to be at risk when said measurement is elevated relative to said control."

However, regarding the instant step of "comparing said measurement to a control to identify a patient as being at risk for atherosclerosis, wherein said patient is identified to be at risk when said measurement is elevated relative to said control", Ramsis et al disclose (1) comparing platelet activity measurements in a healthy control patient to platelet activity measurements in a patient with atherosclerosis and (2) disclose "[Conclusion: This study demonstrates that platelet circulate in an enhanced activation state in asymptomatic atherosclerosis, which is closely related to the degree of endothelial cell damage as expressed by increased plasma levels of TM. The detection

of *platelet activation can be used as a potential marker for oncoming atherosclerosis.*]". See the entire Abstract.

Hence, Carr discloses or suggests the invention claimed except for the step of "comparing platelet activity measurements in a control to a patient being at risk to atherosclerosis" step provided by Ramsis et al.

Therefore, it would have been obvious to one having ordinary skill in this art at the time this invention was made to provide the invention claimed because Carr discloses or suggests the invention as claimed except for the step of "comparing platelet activity measurements in a control to a patient being at risk to atherosclerosis" step provided by Ramsis et al earlier.

(III). Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al (US 4,986,964)(1993) in view of Ramsis et al.

Carr et al disclose or suggest a method for identifying patients at risk for atherosclerosis. Carr et al disclose method for identifying patients at risk for atherosclerosis; identifying patients having a bleeding risk; and a treatment monitoring method wherein a measurement on the blood sample is selectively determined by platelet contractile force or clot elastic modulus. As a result, Carr et al disclose or suggest the claim limitations described in the present invention. Therefore, Carr et al disclose or suggest the invention as claimed except for addressing "comparing said

measurement to a control to identify a patient as being at risk for atherosclerosis, wherein said patient is identified to be at risk when said measurement is elevated relative to said control."

However, regarding the instant step of "comparing said measurement to a control to identify a patient as being at risk for atherosclerosis, wherein said patient is identified to be at risk when said measurement is elevated relative to said control", Ramsis et al disclose (1) comparing platelet activity measurements in a healthy control patient to platelet activity measurements in a patient with atherosclerosis and (2) disclose "[Conclusion: This study demonstrates that platelet circulate in an enhanced activation state in asymptomatic atherosclerosis, which is closely related to the degree of endothelial cell damage as expressed by increased plasma levels of TM. The detection of *platelet activation can be used as a potential marker for oncoming atherosclerosis*.]". See the entire Abstract.

Hence, Carr et al disclose or suggest the invention claimed except for the step of "comparing platelet activity measurements in a control to a patient being at risk to atherosclerosis" step provided by Ramsis et al.

Therefore, it would have been obvious to one having ordinary skill in this art at the time this invention was made to provide the invention claimed because Carr et al disclose or suggest the invention as claimed except for the step of "comparing platelet activity measurements in a control to a patient being at risk to atherosclerosis" step provided by Ramsis et al earlier.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is 571-272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LOUISE N. LEARY
PRIMARY EXAMINER

January 19, 2006